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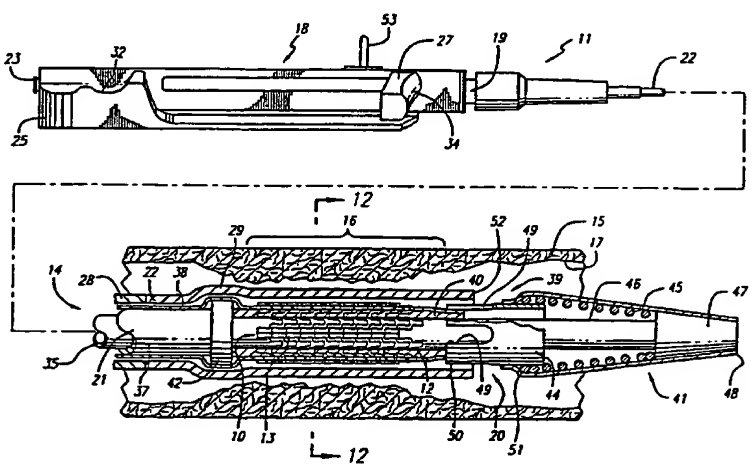

(57) Abstract

The invention is directed to a self-expanding stent for implantation into a body lumen, such as an artery. The stent consists of a plurality of radially expandable cylindrical elements generally aligned on a common longitudinal stent axis and interconnected by a plurality of interconnecting members placed on the stent in a collinear arrangement such as to create at least one continuous spine which extends along the length of the stent. The invention also is directed to a stent delivery system for implantation of a stent in a vessel which includes an outer tubular member having a restraining sheath and an inner tubular member having a distal end which has a compressed stent mounted thereto. The proximal end of the inner tubular member is connected to a housing assembly which prevents the inner tubular member from moving when the outer tubular member is retracted to deploy the stent. The proximal end of the outer tubular member is attached to a pull-back handle which is slidably mounted on the base of the housing assembly. When the pull-back handle is retracted, the restraining sheath is retracted to deploy the sheath, while the inner tubular member remains stationary.

SELF-EXPANDING STENT WITH ENHANCED DELIVERY PRECISION AND STENT DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

The present invention relates to expandable endoprosthesis devices, generally called stents, which are adapted to be implanted into a patient's body lumen, such as a blood vessel, to maintain the patency thereof, along with systems for delivering and deploying such stents. Stents particularly are useful in the treatment and repair of blood vessels after a stenosis has been compressed by percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal angioplasty (PTA), or removed by atherectomy or other means, to help improve the results of the procedure and reduce the possibility of restenosis.

Stents are generally cylindrically-shaped devices which function to hold open and sometimes to expand a segment of a blood vessel or other arterial lumen, such as coronary artery. Stents usually are delivered in a compressed condition to the target site and then deployed at that location into an expanded condition to support the vessel and help maintain it in a patent or an open position. Stents particularly are suitable for use to support and to hold back a dissected arterial lining which, unless treated, can occlude the fluid passageway through the artery.

A variety of devices are known in the art for use as stents and include coiled wires in a variety of patterns that are expanded after being placed intraluminally on a balloon catheter; helically-wound coiled springs manufactured from an expandable heat-sensitive metal; and self-expanding stents that are inserted into the body in a compressed state for deployment into a body lumen. One of the difficulties encountered in using prior art stents has been maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent, which longitudinal flexibility facilitates delivery of the stent and accommodates the often tortuous path of the patient's vasculature.

Prior art stents typically fall into two general categories of construction. The "expandable" type of stent is expandable upon application of a controlled force,

often applied by inflation of a balloon portion of a dilatation catheter which force, upon inflation of the balloon or other expansion means, expands the compressed stent to a larger diameter to be left in place within the artery at the target site. The "self-expanding" type of stent will automatically expand from a compressed state when the stent is advanced out of the distal end of the delivery catheter into the blood vessel. Self-expanding stents can be formed from shape memory metals or super-elastic nickel-titanum (NiTi) alloys (nitinol). Self-expanding stents manufactured from expandable heat-sensitive materials allow for phase transformations of the material to occur, resulting in the expansion and contraction of the stent.

Details of prior art expandable stents can be found in U.S. Patent No. 3,868,956 (Alfidi et al.); U.S. Patent No. 4,512,1338 (Balko et al.); U.S. Patent No. 4,553,545 (Maass, et al.); U.S. Patent No. 4,733,665 (Palmaz); U.S. Patent No. 4,762,128 (Rosenbluth); U.S. Patent No. 4,800,882 (Gianturco); U.S. Patent No. 5,514,154 (Lau, et al.); U.S. Patent No. 5,421,955 (Lau et al.); U.S. Patent No. 5,603,721 (Lau et al.); U.S. Patent No. 4,655,772 (Wallsten); U.S. Patent No. 4,739,762 (Palmaz); and U.S. Patent No. 5,569,295 (Lam).

Further details of prior art self-expanding stents can be found in U.S. Patent No. 4,580,568 (Gianturco); and U.S. Patent No. 4,830,003 (Wolff, et al.).

Some prior art stent delivery systems for implanting self-expanding stents include an inner lumen upon which the compressed or collapsed stent is mounted and an outer restraining sheath which is initially placed over the compressed stent prior to deployment. When the stent is to be deployed in the body vessel, the outer sheath is moved relative to the inner lumen to "uncover" the compressed stent, allowing the stent to release into the expanded condition. Some delivery systems utilize a "push-pull" deployment method in which the outer sheath is retracted while the inner lumen is pushed forward. Still other systems use an actuating wire which is attached to the outer sheath. When the actuating wire is pulled to retract the outer

sheath and deploy the stent, the inner lumen remains stationary, preventing the stent from moving axially within the body vessel.

However, there are disadvantages associated with the use of prior art delivery systems. For example, systems which rely on a "push-pull design" can result in the collapsed stent moving within the body vessel when the inner lumen is pushed forward which can lead to inaccurate positioning and, in some instances, possible perforation of the vessel wall by a protruding end of the stent. Delivery systems which utilize an actuating wire design can tend to move to follow the radius of curvature when placed in curved anatomy of the patient. As the wire is actuated, tension in the delivery system can cause the system to straighten. As the system straightens, the position of the stent changes because the length of the catheter no longer conforms to the curvature of the anatomy. This change of the geometry of the system within the anatomy also can lead to inaccurate positioning of the stent.

Another difficulty which can be encountered with some existing self-expanding stents is the fact that the length of the stent can shorten dramatically during deployment, making it difficult to precisely position the stent within the artery. Because proper positioning of the stent is critical to the performance of the stent, it is imperative that the physician know the exact length and diameter to which the stent will expand to upon deployment. A self-expanding stent which shortens in length upon radial expansion of the device can frustrate the physician who is attempting to accurately position the stent within the target site. Additionally, some existing self-expanding stents can store energy axially as the outer restraining sheath is retracted. Frictional force generated as the outer sheath is retracted over the self-expanding stent can cause the stent to act somewhat like a spring, storing energy as the frictional force acts on the stent. The stored energy is released as the stent expands beyond the end of the sheath, and this release of energy can cause the stent to move or "jump" from the desired position, resulting in inaccurate placement. The amount of energy stored is dependent on, among other

things, the inherent flexibility of the stent and the friction between the stent and the outer sheath.

The above-described stent delivery systems also can be somewhat difficult to operate with just one hand, unless a mechanical advantage system (such as a gear mechanism) also is provided. Deployment with one hand often is desirable because it allows the physician to use his/her free hand to support the guiding catheter, the position of which is critical to the procedure, and the use of this free hand allows the physician to prevent the guiding catheter from moving during deployment of the stent. The above-described prior art stent delivery systems do not have features that are designed to prevent any axial movement of the catheters during stent deployment. Even a slight axial movement of the catheter assembly during deployment can lead to inaccurate placement of the stent in the body lumen.

What has been needed and heretofore unavailable is a self-expanding stent which has a high degree of flexibility so that the stent can be advanced through tortuous passageways of the anatomy, then expanded up to its maximum diameter with minimal or no longitudinal contraction, and yet have sufficient mechanical strength to hold open the body lumen. The self-expanding stent also should store little or no energy during sheath retraction in order to prevent "jumping" of the stent from occurring, to permit more accurate positioning of the stent within the body lumen. Also, there is a need for a stent delivery system which encourages minimal movement of the stent while it is being deployed, provides for accurate placement of the stent, and allows single-handed operation by the physician. The present invention satisfies all of these needs.

SUMMARY OF INVENTION

The present invention is directed to a self-expanding stent having a configuration which permits the stent to be expanded radially to larger diameters without significant longitudinal shortening of the stent during expansion. The

present invention thus provides a stent which maintains a constant length from its fully compressed condition all the way through to its fully expanded condition. A self-expanding stent in accordance with the present invention provides for more accurate placement in the process of delivering the stent to the target site in the body lumen. The stent remains relatively flexible along its longitudinal axis in order to facilitate delivery through tortuous body lumens, but nonetheless is strong enough radially in its expanded condition to maintain the patency of the body lumen, such as an artery or other vessel, when implanted therein.

The stent of the present invention also minimizes the potential for storing energy as the outer restraining sheath of the stent delivery catheter is retracted over the compressed stent. The structure of the stent made in accordance with the present invention stores little or no energy during deployment, reducing the likelihood that the stent will "jump" off of the delivery catheter when the last of the sheath-covered portion is being released. As a result, a smooth and controlled deployment can be achieved when utilizing the stent of the present invention. This stent design results in a low profile device which maintains good flexibility to reach even the distal-most lesions in a patient's vasculature.

The stent of the present invention includes a plurality of adjacent cylindrical elements (also referred to as "rings") which are independently expandable in the radial direction and which are arranged along a common longitudinal axis. The cylindrical elements are formed in an irregular serpentine wave pattern transverse to the longitudinal axis and continuing in a plurality of alternating peaks and valleys. Each cylindrical element is connected to an adjacent cylindrical element by at least one interconnecting member which interconnecting member is aligned longitudinally with another interconnecting member to create a continuous spine which runs the length of the stent to prevent any significant stent shortening during expansion. The continuous spine also helps to prevent an undesirable store of potential energy in the stent which may cause the stent to "jump" as the outer restraining sheath of the delivery catheter is retracted to deploy the stent.

In one preferred embodiment of the present invention, each cylindrical element is connected to an adjacent cylindrical element by three interconnecting members which are circumferentially positioned 120° apart. In this embodiment, the interconnecting members are aligned to form three continuous spines along the length of the stent, again the spines so configured to prevent any significant shortening of the stent during radial expansion and to prevent any unwanted storage of energy as the outer restraining sheath is retracted for deployment.

The presently preferred structure for the expandable cylindrical elements which form the stent of the present invention generally is characterized by a circumferential serpentine pattern along a plurality of alternating peaks and valleys. Each cylindrical element contains three (3) "W" and three (3) "U" shaped patterns which form the valleys of the stent. Each "W" and "U" shaped valley is connected by an inverted "U" shaped pattern which forms the peaks of the cylindrical element. As the stent expands, the "W", and "U" and inverted "U" patterns open circumferentially, with the interconnecting members maintaining the spacing between each cylindrical element. To minimize the gaps between the struts when the stent is expanding, each serpentine cylindrical element is designed to extend into the space between the "W", the "U" and the inverted "U" of an adjacent cylindrical element. The interconnecting members insure minimal longitudinal contraction during radial expansion of the stent in the body vessel. Preferably, the serpentine patterns have varying degrees of curvature in the regions of the peaks and valleys and are adapted so that radial expansion of the cylindrical elements are generally uniform around their circumferences during expansion of the stent from the contracted condition to the expanded condition.

The resulting stent structure is a series of radially expandable cylindrical elements that are spaced closely enough longitudinally so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall, yet are not so closely spaced as to compromise the longitudinal flexibility of the stent both when the stent is being negotiated through the patient's vasculature in the

unexpanded state and when the stent is expanded into position at the target site in a particular body lumen. The serpentine patterns allow for even expansion around the circumference by accounting for the relative differences in stress created by the radial expansion of the cylindrical elements. Each of the individual cylindrical elements may rotate slightly relative to their adjacent cylindrical elements without significant deformation, cumulatively providing a stent which is flexible along its length and longitudinal axis, but which still is very stable in the radial direction so as to resist collapse after expansion. The open reticulated structure of the stent results in a low mass device. It also enables the perfusion of blood over a large portion of the arterial wall, which can improve the healing and repair of a damaged arterial lining.

The stent of the present invention can be laser cut from a tube of nitinol, the transformation temperature of which is below body temperature. All of the stent diameters are cut with the same stent pattern, and the stent is expanded and heat treated to be stable at the desired final diameter. The heat treatment also controls the transformation temperature of the nitinol such that the stent is super elastic at or below body temperature. The stent is electro-polished to obtain a smooth finish with a thin layer of titanium oxide placed on the surface. The stent usually is implanted into a target vessel which is smaller in diameter than the diameter of the stent so that the stent will apply a force to the vessel walls to keep the vessel open upon deployment.

After the stent is expanded, some of the peaks and/or valleys may, but will not necessarily, tip outwardly and embed in the vessel wall. Thus, after expansion, the stent might not have a smooth outer wall surface. Rather, the stent might exhibit small projections which embed in the vessel wall and which aid in retaining the stent in place in the vessel.

The elongated interconnecting members which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements.

The interconnecting members may be formed in a unitary structure with the expandable cylindrical elements formed from the same intermediate product. The stent also could be made from a sheet of material with the pattern of the cylindrical elements and interconnecting elements cut by a laser. The sheet then could be formed into a cylinder by welding a longitudinal seam using laser welding or other known techniques.

Preferably, the number and location of the interconnecting members can be varied in order to develop the desired longitudinal flexibility provided by the rings in the stent structure both in the compressed condition as well as in the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stents, the more easily and more safely the stents can be delivered to the implantation site, especially when the implantation site is on a curved section of a body lumen, such as a coronary artery or a peripheral blood vessel and, especially saphenous veins and larger vessels. The number of spines formed by the collinear arrangement of interconnecting elements can vary from one spine to as many spines as can be reasonably placed on the stent. However, for minimal energy storage with maximum flexibility, two to four spines are preferred.

The stent of the present invention is particularly useful for implantation in body lumens which are located along the outer portions of the body where external forces could possibly be applied to the stent. For example, the stent of the present invention is particularly advantageous for implanting in the carotid arteries, which are susceptible to external forces. Because the nitinol stent is crush resistant, the stent will spring back to its original expanded condition even after an external force is applied to it. As a result, there is less likelihood that the stent will be permanently deformed or crushed by an external force. Additionally, due to the springy and softer composition of the stent, there is less likelihood that the struts of the stent

would cut into any underlying plaque upon application of an external force. If the struts were to cut into underlying plaque, small pieces of the plaque might be dislodged and then undesirably would enter the bloodstream.

The present invention also is directed to a stent delivery system which can be used to accurately deploy a self-expanding stent into a target site in a patient's body lumen. The stent delivery system in accordance with the present invention incorporates unique features which discourage the stent from any undesirable movements during stent deployment, aid in accurate placement of the stent, and permit single-handed system operation. The stent delivery system can be used to deploy the novel self-expanding stent disclosed herein, or any self-expanding stent.

One preferred embodiment of a stent delivery system made in accordance with the present invention includes an elongated catheter body having a proximal end and a distal end. The elongated catheter body is made up of an inner tubular member which extends within an outer tubular member in a coaxial arrangement. The outer tubular member has a restraining sheath at its distal end which holds the stent, which is mounted on the inner tubular member, in its compressed delivery position until the stent is ready for deployment. The outer tubular member and the restraining sheath are retractable to release the compressed stent to its expanded condition. The proximal ends of the inner and outer tubular members are connected to a housing assembly which provides a manual mechanism for retracting the restraining sheath and for immobilizing the inner tubular member, preventing the inner tubular member from moving relative to the restraining sheath during stent deployment. The proximal end of the outer tubular member is attached to a pull-back handle located on the housing assembly which is moved by the physician in order to retract the restraining sheath and thus to deploy the compressed stent. A luer fitting, attached to the proximal end of the inner tubular member, is rigidly fixed to the housing base so as to prevent the inner tubular member from moving when the outer tubular member is retracted.

The inner tubular member has a guide wire lumen which extends from the distal end of the inner tubular member to the proximal end of the inner tubular member to allow a guide wire to be used to advance the elongated catheter body to the target area in the body lumen in an "over-the-wire" technique. Using this approach, the catheter stent assembly can be introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter. The distal end of the inner tubular member includes a soft, low-profile tip assembly with a radiopaque marker. An additional radiopaque marker is placed proximally to the collapsed stent.

In a preferred embodiment of the present invention, the inner tubular member is made with three (3) coaxial layers of materials. The innermost layer is the guide wire lumen (described above) which runs the entire length of the catheter body. The second layer of the inner tubular member is composed of a proximal portion made from stainless steel hypotubing and a distal, reinforcing portion which can be made from a material with high compressive strength such as polyetheretherketone (PEEK). The outermost part of the inner tubular member is formed from thin-layered shrink tubing.

In a preferred embodiment, the tip assembly of the inner tubular member includes a tubular element made from a piece of stainless steel hypotubing to which a wound coil is welded. The coil and the distal end of the tubular element are encased in molded urethane. The distal end of the urethane body is loaded with radiopaque tungsten, which makes radiopaque the tip of the delivery system. The proximal end of the tubular segment can include circumferential slots, which are cut into the proximal end in order to provide a channel that allows air and fluid to escape when the catheter assembly is flushed to evacuate air from the system.

The housing assembly of the stent delivery system is designed so that the operator retracts only the outer restraining sheath while the inner tubular member remains stationary. Due to the unique design of the housing assembly, the physician pushes down on the housing assembly during deployment rather than pushing the

housing assembly forward. This feature prevents the inner tubular member assembly from moving forward toward the patient. The housing assembly includes a uniquely curved base which has a contour which conforms to the patient's leg. The design of the housing allows the system to be operated by just one hand, freeing the physician's other hand for other purposes, such as the purpose of keeping the position of the guiding catheter stable during deployment of the stent.

The stent delivery system of the present invention also includes a unique flushing system which is used to evacuate air from the system. The flushing system consists of small openings which extend through the inner tubular member near the end of the proximal portion where the proximal portion meets the distal portion of the inner member. The openings are drilled through the guide wire lumen to effectively open up a passageway from the guide wire lumen to the annular space that is formed between the inner tubular member and the outer tubular member. A syringe is attached to the luer fitting at the housing assembly and sterile fluid is pumped into the guide wire lumen in order to flush air from the system. A mandrel placed in the guide wire lumen at the tip assembly blocks the flow of the sterile fluid through the distal tip. The sterile fluid thus is forced to flow out of the small openings into the annular space formed between the inner tubular member and the outer tubular member. The fluid flows past the collapsed stent where the fluid eventually will escape either through the small circumferential slots cut into the tubular element of the tip assembly or from the sheath directly. When fluid is observed dripping from the end of the restraining sheath, this is an indication that air has been evacuated from the system. Thus, at this point, the mandrel can be removed. Because the gap sizes are so small between the various components, capillary force prevents air from infiltrating the delivery system once the initial evacuation of the systems has been performed.

These and other advantages of the present invention will become apparent from the following detailed description and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view, partially in section, depicting a self-extending stent in accordance with the present invention mounted on a stent delivery system in accordance with the present invention, the self-expanding stent and the stent delivery system being disposed within a vessel, the self-expanding stent in the compressed condition.

FIG. 2 is an elevational view, partially in section, depicting the self-expanding stent and stent delivery system of FIG. 1, wherein the self-expanding stent is in the expanded condition.

FIG. 3 is a plan view showing the housing assembly of the stent delivery system shown in FIG. 1 in the locked position.

FIG. 4 is a plan view of the housing assembly of the stent delivery system shown in FIG. 1 in the unlocked position.

FIG. 5 is a cross-sectional view of the housing assembly of FIG. 4 taken along the lines 5-5.

FIG. 6 is a cross-sectional view of the housing assembly of FIG. 4, taken along the lines 6-6.

FIG. 7 is an elevational view of the inner tubular member of the catheter portion of a stent delivery system in accordance with the present invention.

FIG. 8 is an elevational view showing the housing assembly of a stent delivery system in accordance with the present invention as the housing would appear when being manually operated.

FIG. 9 is a plan view of a preferred embodiment of a stent according to the present invention, with the stent flattened so as to illustrate the serpentine pattern in which the interconnecting members are arranged collinearly to form a continuous spine along the stent.

FIG. 10 is an enlarged partial view of the stent of FIG. 9 depicting the serpentine pattern along the peaks and valleys which form a cylindrical element of a stent in accordance with the present invention.

FIG. 11 is a cross-sectional view of the inner tubular member of FIG. 7, taken along the lines 11-11.

FIG. 12 is a cross-sectional view of the catheter body shown in FIG. 1, taken along the lines 12-12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a self-expanding stent which permits delivery with enhanced precision and a stent delivery system for accurately placing self-expanding stents into a target site in a body lumen. While the present invention is described in detail as applied to the coronary arteries of a patient, those skilled in the art will appreciate that the invention also can be used in other body lumens as well, such as the peripheral arteries, including the carotid arteries, and the veins.

FIGS. 1-4 illustrate a self-expanding stent 10 incorporating features of the present invention. The stent 10 is mounted onto a stent delivery system 11 which

also is in accordance with the present invention. The stent 10 generally comprises a plurality of radially expandable cylindrical elements 12 which are disposed generally coaxially and which are connected by interconnecting members 13 disposed between adjacent cylindrical elements 12. Additional details regarding the particular structure and shape of the various structures making up the stent 10 are provided below.

The stent delivery system 11 has an elongated catheter body 14 for delivering and deploying the compressed stent 10 (i.e., in the state the stent is shown in FIG. 1) within an artery 15 or other vessel. The artery 15, as shown in FIGS. 1 and 2, has a treated area 16 which has undergone an angioplasty procedure, or similar procedure, in which the atherosclerotic plaque of a stenosis has been compressed against the inside wall 17 of the artery 15 in order to increase the diameter of the occluded area of artery 15. The expanded stent 10 (i.e., in the state the stent is shown in FIG. 2) is implanted within the artery 15 to help hold open the artery in this area and to help prevent restenosis.

The stent delivery system 11 includes a housing assembly 18 attached to the proximal end 19 of the elongated catheter body 14 which is used to manually deploy the compressed stent 10 mounted on the distal end 20 of the catheter body 14 into the diseased artery 15. The catheter body 14 includes an inner tubular member 21 which extends within an outer tubular member 22 in a coaxial arrangement. The inner tubular member 21 has a luer fitting 23 attached at its proximal end 24 which can be rigidly attached to the base 25 of the housing assembly 18 in order to prevent the inner member 21 from moving relative to the outer member 22 during stent deployment. The outer tubular member 22 of the catheter body 14 has a proximal end 26 that can be attached to a pull-back handle 27 on the housing assembly which pull-back handle is designed to move axially (i.e., along the longitudinal axis of the catheter body 14) within the base 25. At the distal end of the outer tubular member 22 is a flexible restraining sheath 29 which is welded or otherwise is attached to the elongated shaft 28 of the outer tubular member 22. The restraining sheath 29 is

designed to hold the stent 10 in the compressed or collapsed state until the time of deployment of the stent. The restraining sheath 29 is retracted by moving the pull-back handle 27 away from the delivery system (i.e., in the direction of the arrows 30 which are shown in FIG. 4) which moves the restraining sheath in a like direction, but maintains the inner tubular member 21 stationary while the stent is deployed.

FIG. 8 illustrates how the pull-back handle 27 of the housing assembly 18 can be grasped by just one of the physician's hands 31 in order to deploy the collapsed stent 10. The housing assembly 18 includes a pair of thumb grooves 32 which are located at the proximal end 33 of the base 25 and which are adapted to receive the thumb of one of the physician's hands when the physician gets ready to deploy the stent. The pull-back handle 27 includes a pair of recesses 34, only one of which can be seen in FIG. 8, which recesses 34 are adapted for the fingers of the physician. The physician simply pulls back on the pull-back handle 27 to deploy the stent 10, once the stent 10 has been moved into the desired position. Because the thumb grooves 32 will hold the physician's thumb in a plane that is roughly perpendicular to the longitudinal axis of the restraining sheath, the housing assembly discourages the physician from pushing longitudinally forward to move the housing assembly towards the patient. Rather, to the extent the force of the physician's thumb moves the housing assembly at all, it will likely move the housing assembly downward. When the force on the housing translated through the physician's thumb on the pull-back handle is directed downwardly, the distal end of the catheter body 14 should be prevented from moving around in the artery so that, upon retraction of the sheath 29, the stent will be placed accurately at the intended location in the body lumen. Because the stent delivery system 11 can be operated with just one hand, the physician can use his or her free hand to perform other tasks, such as the task of stabilizing the guiding catheter through which the stent delivery system 11 has been introduced into the patient's body. When the guiding catheter can be stabilized, this also enhances the accuracy with which a stent 10 can be

deployed using the delivery system 11 of the invention. Details concerning additional features of the housing assembly 18 are provided below.

In one embodiment of the present invention, and referring now to FIG. 7, the inner tubular member 21 is a composite structure formed from three (3) coaxial layers of materials, each material having a specific function. The innermost layer is a guide wire lumen 35 which runs the entire length of the catheter body 14. This guide wire lumen 35 can be made from a material such as a high density polyethylene (HDPE) or similar material which provides a low-friction interface between the delivery catheter and the guide wire (not shown) which also is used in the procedure to advance the catheter body 14 to the target site using over-the-wire techniques that are well known in the art. For example, the guide wire lumen 35 can be made from tubing which is compatible with a 0.36 mm (.014 in.) guide wire for an over-the-wire configuration.

The application of tensile force to the shaft of the outer tubular member 22 and to the restraining sheath 29 during stent deployment creates an equal and opposite compressive force on the inner tubular member 21. For the restraining sheath 29 to retract (via the movement of the pull-back handle 27) without causing the rest of the catheter body 14 to buckle, the inner tubular member 21 must possess sufficient column strength to prevent buckling or deformation. Otherwise, buckling or deformation of the inner tubular member 21 can cause the distal end 20 of the delivery catheter 14 to move within the artery, with the consequence of inaccurate deployment of the stent. Therefore, the second layer of the inner tubular member may be comprised of tubular elements which possess sufficient rigidity to prevent unwanted buckling or deformation of the catheter body, yet which are flexible enough to track along the torturous anatomy to the target site.

In a preferred embodiment of the present invention, the second layer of the inner tubular member 21 includes a proximal portion 36 which is made from a stainless steel hypotube, or similar material, and a distal portion 37 comprised of more flexible material such as polyethereketone (PEEK) or a similar material that

possesses excellent compressive strength yet which is reasonably flexible. The proximal portion 36 is made from hypotubing which provides maximum strength, but which is fairly rigid. However, this is not a concern because this proximal portion 36 of the inner tubular member 21 remains relatively straight within the guiding catheter during the procedure. The distal portion 37, which is approximately 15 cm in length, must exit the guiding catheter and track through the torturous anatomy to reach the target site. Therefore, this portion must possess sufficient compressive strength yet also must be fairly flexible.

The outermost layer of the inner tubular member 21 may be made from a layer of shrink tubing 38 having low friction characteristics. A suitable material would be linear low density polyethylene (LLDPE). The outer layer of shrink tubing 38 is used to reduce the amount of friction that is created when the outer tubular member 22 is retracted over the length of the inner tubular member 21. The outer surface of the inner tubular member 21 also can be coated with a silicone lubricant such as that manufactured under the tradename MICROGLIDE by Advanced Cardiovascular Systems, Inc. of Santa Clara, California, to further reduce the amount of frictional buildup between the outer tubular member 22 and the inner tubular member 21.

The luer fitting 23 of the housing assembly 18 that is attached to the proximal portion 36 of the inner tubular member 21 is rigidly mounted to the base 25 of the housing assembly 18, in order to secure the inner member to the housing assembly throughout the procedure. The luer fitting 23 can be permanently attached to the inner tubular member 21 by trimming the guide wire lumen 35 at the proximal end and then by gluing the luer fitting 23 and the proximal portion 36 of the inner tubular member together with a suitable adhesive. It should be appreciated that mounting the inner tubular member to the housing assembly 18 can be achieved in any number of ways without departing from the scope of the present invention.

The distal end 39 of the inner tubular member 21 includes a stent holder 40 about which the compressed stent 10 is mounted. A tip assembly 41 having a

tapered configuration is located at the distal end of the delivery catheter 14 to help the stent delivery system 11 cross areas of occlusions in the diseased artery. A tantalum marker 42 is attached to the proximal end of the stent holder 40 by an adhesive or by some other appropriate means. The tantalum marker 42 is radiopaque and can be used by the physician to locate the proximal end of the stent 10 on a radiograph during the procedure. In addition, the tantalum marker 42 is larger than the inner diameter of the compressed stent 10 so as to provide an abutting surface against which the stent 10 can push when the restraining sheath 29 is being retracted, thus discouraging the stent 10 from withdrawing with the sheath. The stent holder 40 can be made from a piece of tubing which correctly sizes the mismatch between the inner diameter of the collapsed stent 10 and the rest of the inner tubular member 21. The tubing can be a composite material such as a mix of 75% LLDPE, which makes the stent holder soft and flexible, and 25% HDPE, which will contribute to the pushability of the delivery system. The stent holder 40 has a tapered distal tip 43 to facilitate attachment to the tip assembly 41. The stent holder 40 can be glued directly onto the guide wire lumen 35 of the inner tubular member 21and is encased under the layer of shrink tubing 38 which forms the outermost layer of the inner tubular member 21.

The tip assembly 41 is characterized by a tubular element 44 or mounting segment, that is formed from a small segment of stainless steel hypotube, and a tapered wound coil 45, that is welded to the distal end of the tubular element 44. The tapered wound coil 45 and the distal end of the mounting segment 44 are encased in molded urethane to form a tip component 46. A radiopaque tungsten element 47 is placed at the distal end of the tip component 46. The guide wire lumen 35 extends through the tip component to the distal tip 48. An opening (not shown) at the distal end of the tip assembly 41 permits the guide wire to advance out of the stent delivery system 11 to allow the catheter body 14 to track along the wire into the diseased artery.

The tubular element 44 has a number of circumferential slots 49 cut into the proximal end of the tubular element 44. The slots 49 provide a channel which allows fluid to escape when the device is being flushed in order to evacuate air from the delivery system. The proximal end 50 of the tubular element 44 abuts the distal end of the stent holder 40 and this proximal end is partially covered by the restraining sheath 29. During the procedure in which air is evacuated from the stent delivery system 11, at least a small segment of the slots 49 should be unsheathed to allow the flushing fluid and air to escape from the system. The tip component 46 includes a shoulder 51 which is raised from the outer surface of the tubular element 44 so that the distal end 52 of the restraining sheath 29 will remain flush with the tip component 46. This particular configuration prevents the distal end 52 of the restraining sheath 29 from being exposed while the delivery catheter is being maneuvered through the curves of the anatomy.

The elongated shaft 28 of the outer tubular member 22 can be made from a material such as cross-linked HDPE. The restraining sheath 29 can be made from a material such as a polyolefin, and welded or otherwise attached to the shaft 28 of the outer tubular member. A material such as a polyolefin is desirable as this material has sufficient strength to hold the stent in the compressed state and is characterized by relatively low friction, thus minimizing the friction that might be created between the stent 10 and the restraining sheath 29. Friction can be reduced further by applying a coat of silicone lubricant, such as MICROGLIDE, to the inside surface of the restraining sheath 29 before the stent 10 is loaded onto the stent holder 40.

Referring now to FIGS. 3-6, the housing assembly 18 is shown including a lock mechanism 53 which locking mechanism is designed to maintain the pull-back handle 27 in its forward position until the physician is ready to deploy the stent. The base of the housing assembly 18 includes a cover 54 which extends from the distal end of the base 25 to the proximal end of the base. This cover 54 includes an opening 55 for receiving the lock mechanism 53. The lock mechanism 53 is

operated by simply grasping a control knob 56 and rotating the control knob either to the locked or the unlocked position. FIGS. 3 and 5 show the lock mechanism 53 in the locked position. In the locked position, a shoulder portion 57 of the lock mechanism 53 comes into contact with a raised projection 58 that is formed on the pull-back handle 27. The shoulder portion 57 includes a slotted opening 59 through which the raised projection 58 slides when the pull-back handle 27 is retracted to deploy the stent. The shoulder portion 57 abuts the raised projection 58 preventing the raised projection 58 from moving past the shoulder portion 57, since the slotted opening 59 is oriented so as to be approximately 90° out of phase with the raised protection 58. Referring now to FIGS. 4 and 6, which show the lock mechanism in the unlocked position, the slotted opening 59 on the shoulder portion 57 is now aligned with the raised projection 58 so as to allow the raised projection 58 to pass through the shoulder portion 57. In the open position shown in FIG. 4 and 6, the lock mechanism 53 allows the pull-back handle 27 to be pulled back in direction of the arrow 30, which action then retracts the restraining sheath to and thus deploys the stent.

The base 25 of the housing assembly 18 includes a slotted channel 60 which is adapted to receive the central portion 61 of the pull-back handle 27. The central portion 61 includes an opening 62 through which the proximal portion 36 of the inner tubular member 21 extends to a location where the luer fitting 23 is rigidly mounted in a recess (not shown) or to a similar mounting element on the base 25. The proximal end 26 of the outer tubular member 22 is affixed to the front plate 63 of the pull-back handle 27 so that as the pull-back handle is retracted, the outer member 22 and restraining sheath 29 likewise are retracted, accordingly while the inner member 21 remains stationary.

As can be seen in FIGS. 5 and 6, the base 25 has an unique contour which increases the surface area of the base and is contoured to fit the patient's leg. Thus, during the procedure, the physician can place the housing assembly 18 directly onto the leg of the patient where it should remain stationary as the sheath is being

retracted. The unique design of the housing assembly permits the physician to use just one hand to retract the pull-back handle 27 in order to deploy the compressed stent into its expanded condition without the worry of possibly disturbing the position of the entire stent delivery system when the stent is being deployed.

The stent delivery system of the present invention also includes a unique flushing system which can be used to evacuate air from the system. It especially is important to evacuate air from the delivery system when the system is being used to deploy a stent in a carotid artery, because it is undesirable to have even a small air bubble in any of the arteries in the brain. In other instances, it may be desirable to have a fluid preexisting in the system before it is introduced into the patient, so as to prevent blood from accumulating between the retractable sheath and the inner tubular member, as stagnated blood has the tendency to coagulate and cause thrombosis. For this reason, it also may be beneficial to pre-flush the system before placing the delivery catheter in the patient.

Referring now to FIGS. 7, 11 and 12, the flushing system consists of openings 64 extending through the inner tubular member 21 in the area where the proximal portion of the stent holder 40 meets the distal portion of the inner tubular member (FIG. 7). The openings 64 are drilled through to the guide wire lumen 35 to effectively open up a passageway from the guide wire lumen 35 out to the annular space that is formed between the inner tubular member 21and the outer tubular member 22. A syringe can be attached to the luer fitting 23 of the housing assembly 18 and a sterile fluid pumped through the syringe into the guide wire lumen 35 in order to flush air from the system. A mandrel (not shown) desirably is placed in the guide wire lumen 35 at the tip assembly 41 in order to block the flow of the sterile fluid through the distal tip. The sterile fluid thus is forced to flow out of the small openings 64 into the annular space that is formed between the inner tubular member and the outer tubular member. The fluid eventually flows past the collapsed stent (FIG. 12), where the fluid and any air in the system will escape through the small circumferential slots 49 that are cut into the tubular element 44 of

the tip assembly 41. Once fluid is observed dripping from the distal end 52 of the restraining sheath 29, the mandrel can be removed because any air has been evacuated from the system. Because the gap sizes are so small between the various components, capillary force prevents air from re-infiltrating the delivery system once the evacuation has been completed.

Referring now to FIGS. 9 and 10, a preferred embodiment of the stent 10 of the present invention is shown. Referring to FIG. 10, which illustrates a single cylindrical element 12 of the stent 10, a serpentine pattern can be discerned which serpentine pattern is characterized by a plurality of peaks and valleys that aid in the even distribution of expansion forces. In this embodiment, the interconnecting members 13 serve to connect adjacent valleys of each adjacent cylindrical element 12 as described above. The various peaks and valleys generally have "U", "Y", "W", and inverted "U" shapes, in a repeating pattern, and form the cylindrical element 12. During expansion, the double-curved ("W") portions 70, which are located in the region of the valleys where the interconnecting members 13 are connected, have the most mass of the elements comprising the stent and will be the stiffest structure during deformation, while the peak (inverted "U") portions 72 are the least stiff of the elements comprising the stent, and the valley ("U") portions 74 are characterized by an intermediate stiffness. In the embodiment of the stent that is illustrated in FIGS. 9 and 10, there are three repeating patterns of peaks and valleys in each cylindrical element 12, which pattern allows the stent to be crimped down to a very small profile on the stent holder. Each peak (inverted "U") portion 72 has a shoulder portion 75 which shoulder portion 75 is characterized by a different radius of curvature than the radius of curvature for the valley ("U") portions 74 and the peak (inverted "U") portions 72. The shoulder region 75 provides a transition region between the peak (inverted "U") portion 72 and the valley ("U") portions 74 and the double-curved ("W") portion 70 to allow adjacent cylindrical elements to overlap and to thereby better support the artery walls with smaller gaps between the stent struts. In this manner, the shoulder portion 75 allows coverage on the vessel

wall of the serpentine pattern of the cylindrically element to be more dense, thus creating a fairly uniform strut pattern which fully supports the walls of the diseased artery. For this reason, there are none or at least only a few areas of the stent which will not have a strut to support the walls of the artery.

Each interconnecting member 13 is aligned collinearly with each other to form a continuous spine 76 which extends along the length of the stent 10. This continuous spine 76 prevents the stent from shortening longitudinally when the cylindrical elements 12 are expanded radially. The spine 76 also helps prevent the stent from storing energy as the restraining sheath 29 is retracted over the stent during deployment. As a result, the stent 10 will not "jump" off the stent holder 40 as the last few cylindrical elements 12 are released by the restraining sheet 29. Therefore, more accurate deployment of the stent can be achieved. The number and location of the interconnecting members 13 can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the compressed condition as well as the expanded condition. Generally, the greater the longitudinal flexibility of the stent, the more easily and more safely the stent can be delivered to the target site, especially when the implantation site is on a curved section of the body lumen, such as in a coronary artery or a peripheral blood vessel. The number of spines 76 formed by the collinear arrangement of interconnecting elements 13 can vary from one to as many as can be reasonably placed on a stent, however, for a minimal energy storage with a maximum flexibility, two to four spines are recommended.

As shown in FIG. 2, the stent 10 serves to hold open the artery 15 after the catheter body 14 is withdrawn from the artery and helps to reduce the likelihood of restenosis. Due to formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements 12 of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements 12 are pressed into the wall of the artery 15 and do interfere with the blood flow through the artery 15. The cylindrical elements 12 that are pressed into the

wall of the artery 15 eventually will be covered with endothelial cell growth which further minimizes blood flow turbulence. The serpentine pattern of the cylindrical sections 12 provides a good packing characteristic to prevent stent movement within the artery. Moreover, the cylindrical elements 12 closely spaced at regular intervals provide uniform support for the wall of the artery 15. While FIGS. 1 and 2 depict a vessel having an area of compressed plaque, the stent 10 can be used for purposes such as repairing a detached lining in the artery, or assisting in the attachment of a vascular graft (not shown) when repairing an aortic abdominal aneurysm.

The stent of the present invention can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled tubular member, removing portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are left behind to form the stent. It is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser.

Generally, the tubing is put in a rotatable collet fixture of a machine-controlled apparatus for positioning the tubing relative to a laser. According to machine-encoded instructions, the tubing then is rotated and moved longitudinally relative to the laser which also is machine-controlled. The laser selectively removes the material from the tubing by ablation and a pattern is cut into the tube. The tube therefore is cut into the discrete pattern of the finished stent. Further details on how the tubing can be cut by a laser are found in U.S. Patent No. 5,759,192 to Saunders and U.S. Patent No. 5,780,807 to Saunders (Advanced Cardiovascular Systems, Inc.).

The process of cutting a pattern for the stent into the tubing generally is automated except for the loading and the unloading the length of tubing. For example, a pattern can be cut in the tubing using a CNC-opposing collet fixture for axial rotation of the length of tubing, in conjunction with a CNC X/Y table to move the length of tubing axially relative to the machine-controlled laser as described. The entire space between collets can be patterned using the CO_2, Nd or YAG laser

set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the nature of the pattern to be ablated in the coding.

A suitable composition of nitinol used in the manufacture of the stent of the present invention is approximately 55% nickel and 45% titanium (by weight) with trace amounts of other elements making up about 0.5% of the composition. The austenite transformation temperature is between about -15°C and 0°C in order to achieve superelasticity. The austenite temperature is measured by the bend-and-free recover-tangent method. The upper plateau strength is about a minimum of 4138 bars (60,000 psi) with an ultimate tensile strength of a minimum of about 10690 (155,000 psi). The permanent set (after applying 8% strain and unloading), is approximately 0.5%. The breaking elongation is a minimum of 10%. It should be appreciated that other compositions of nitinol can be utilized, as can other self-expanding alloys, to obtain the same features of a self-expanding stent made in accordance with the present invention.

The stent of the present invention can be laser cut from a tube of super-elastic (sometimes called pseudo-elastic) nitinol the transformation temperature of which is below human body temperature. All of the stent diameters are cut with the same stent pattern, and the stent is expanded and heat treated to be stable at the desired final diameter. The heat treatment also controls the transformation temperature of the nitinol such that the stent is super elastic at body temperature. The transformation temperature is at or below body temperature so that the stent is superelastic at body temperature. The stent is electropolished to obtain a smooth finish with a thin layer of titanium oxide placed on the surface. The stent usually is implanted into a target vessel having a diameter which is smaller than the diameter of the stent, so that the stent will apply a force to the vessel wall to keep it open. The stent tubing may be made of suitable biocompatible material besides super-elastic nitinol. In the case of other materials, the stents can be fully-sized but deformed (e.g., compressed) to a smaller diameter onto a balloon of a delivery

catheter in order to facilitate intraluminal delivery thereof to a desired intraluminal site. With nitinol stents, the stress induced by the deformation transforms the stent from an austenite phase to a martensite phase and, when the force which is keeping the stent deformed is removed, the nitinol transforms back into the more stable austenite phase and the stent accordingly expands. Further details of the manner in which nitinol operates are described in U.S. Patent No. 4,665,906 to Jervis and U.S. Patent No. 5,067,957 to Jervis.

The diameter of the stents are very small, given the dimensions of the vessels into which the stents are intended to be deployed. Therefore, the tubing from which the stents are made necessarily also must be characterized by a small diameter. For PTCA applications, a stent typically has an outer diameter on the order of about 1.65 mm (0.065 in.) in the unexpanded condition, which outer diameter corresponds to the outer diameter of the hypotubing from which the stent is made, and the stent can be expanded to an outer diameter of 5.08 mm (0.2 in.) or more. The wall thickness of the tubing is about 0.076 mm (0.003 in.). For stents that are to be implanted in other body lumens, such as in PTA applications, the dimensions of the tubing are correspondingly larger. The hypotubing used for a stent designed for carotid applications typically would have an outer diameter on the order of about 2.4 mm (0.095 in.) with a wall thickness of about 0.18 mm (0.007 in.). The diameter of a stent intended for use in the carotids would be on the order of about 5 to 8 mm. While it is preferred that the stents be made from laser-cut tubing, those skilled in the art will appreciate that the stents also can be laser cut from a flat sheet and then rolled up in a cylindrical configuration with the longitudinal edges welded together to form a cylindrical member.

While the invention has been illustrated and described with respect to intravascular stents, it will be apparent to those skilled in the art that the stents can be used in other instances in all conduits in the body, such as, but not limited to, the urethra and the esophagus. Because the stent of the present invention has the novel feature being able to self-expand to a large diameter without loss of its structural

integrity, it particularly is well suited for implantation in almost any vessel where such devices are used. This feature, coupled with the fact that the stent exhibits limited longitudinal contraction when it is radially expanded, provides a highly desirable support member for all vessels in the body. Other modifications and improvements may be made without departing from the scope of the invention.

WHAT IS CLAIMED IS:

1. A self-expanding stent for implanting in a body lumen having longitudinal flexibility and expandable from a compressed condition to an expanded condition, comprising:

a plurality of adjacent cylindrical elements made from a self-expanding material, each cylindrical element having a circumference extending around a longitudinal stent axis and being substantially independently expandable in the radial direction, wherein the plurality of adjacent cylindrical elements are arranged in alignment along the longitudinal stent axis and form a generally tubular member; and

a plurality of interconnecting members extending between the adjacent cylindrical elements and connecting the adjacent cylindrical elements to one another, wherein some of the interconnecting members are aligned collinearly with respect to each other to form a continuous spine which extends along the length of the stent.

2. The stent of claim 1, wherein the cylindrical elements are formed in a generally serpentine wave pattern transverse to the longitudinal axis and contain alternating valley portions, peak portions, and double-curved portions.

3. The stent of claim 2, wherein the interconnecting members are connected at the double curved portions of each cylindrically element.

4. The stent of claim 1, wherein the plurality of interconnecting members form a plurality of continuous spines which extend along the length of the stent.

5. The stent of claim 3, wherein the plurality of interconnecting members form a plurality of spines which extend along the length of the stent.

6. The stent of claim 1, wherein said stent is formed of a biocompatible material such as super elastic nickel titanium alloy.

7. The stent of claim 1, wherein the stent is formed from a single piece of tubing.

8. A stent delivery system comprising:

a delivery catheter having an inner tubular member having a region for mounting a compressed stent thereon and an outer tubular member having a restraining sheath overlying said inner tubular member and adapted for axial movement with respect to said inner tubular member;

a housing assembly having a pull-back handle slidably mounted on a base, said inner tubular member having a proximal end attached to said base and said outer tubular member having a proximal end attached to said pull-back handle whereby movement of said pull-back handle proximally retracts said restraining sheath proximally from the compressed stent on the inner tubular member, which the inner tubular member remains stationary.

9. The stent delivery system of claim 8, wherein said inner tubular member includes a guide wire lumen extending from the proximal end of the inner tubular member to the distal end of the inner tubular member.

10. The stent delivery system of claim 8 further including a lock mechanism for preventing the pull-back handle from moving proximally until the compressed stent is ready to be deployed.

11. The stent delivery system of claim 8 further including means for evacuating air from the delivery catheter.

12. The stent delivery system of claim 11 wherein an annular space is formed between the outer tubular member and the inner tubular member and further comprising an opening in the inner tubular member which is in fluid communication with the annular space and the guide wire lumen, wherein fluid may be introduced into the guide wire lumen through the opening in the inner tubular member so that the fluid is introduced into annular space and eventually flows through the distal end of the outer tubular member.

13. The stent delivery system of claim 8 wherein the base of the housing assembly has a contoured shape to fit the contour of the leg of a patient.

14. The stent delivery system of claim 8 wherein the housing assembly has a thumb groove located where the proximal end of the base wherein a downward force is applied by the thumb of the user on the thumb groove to help keep the housing assembly stationary during stent deployment.

15. The stent delivery system of claim 8 wherein said inner tubular member has a proximal portion and a distal portion, said proximal portion being made from a compression resistant tubing.

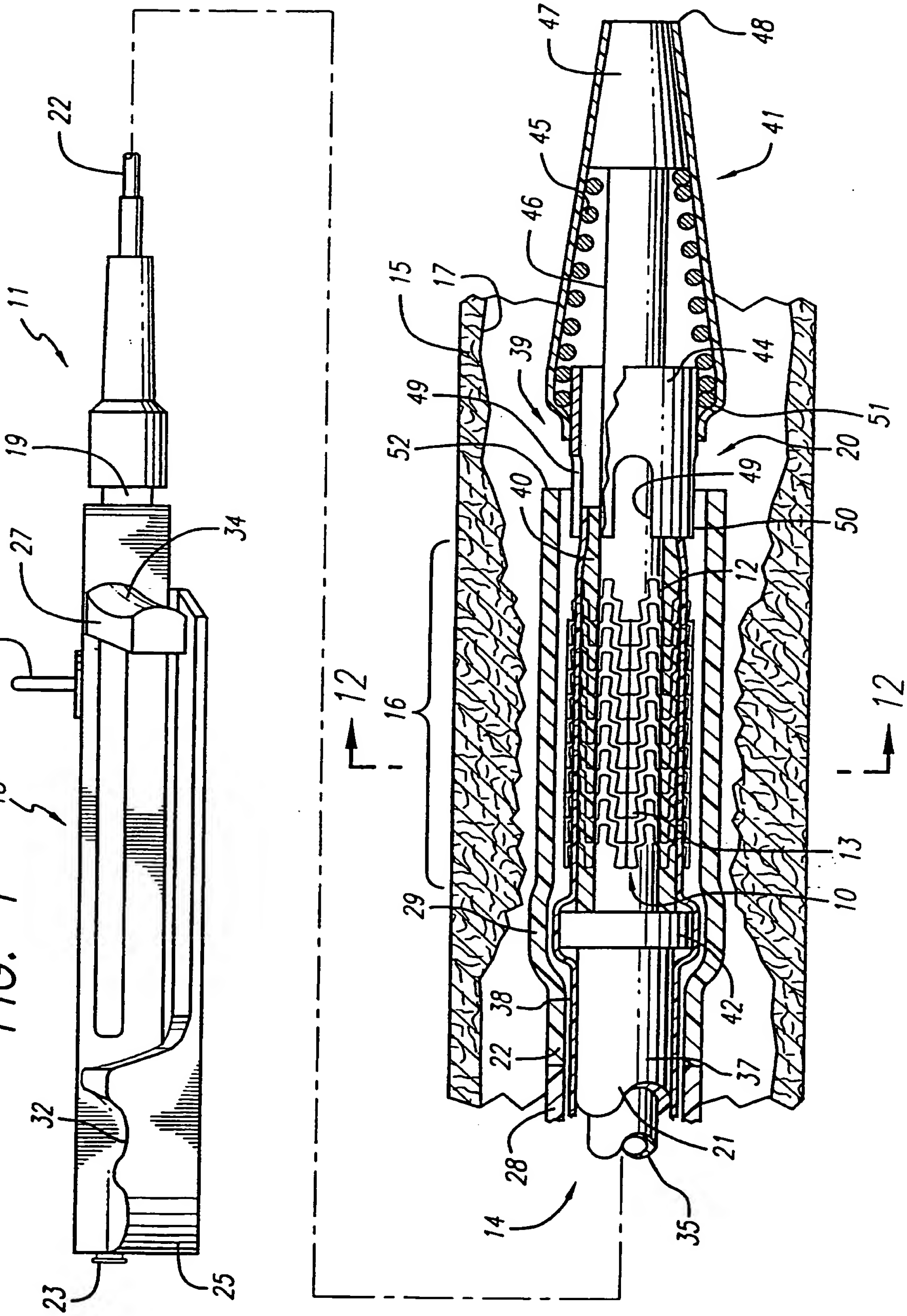
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FIG. 1

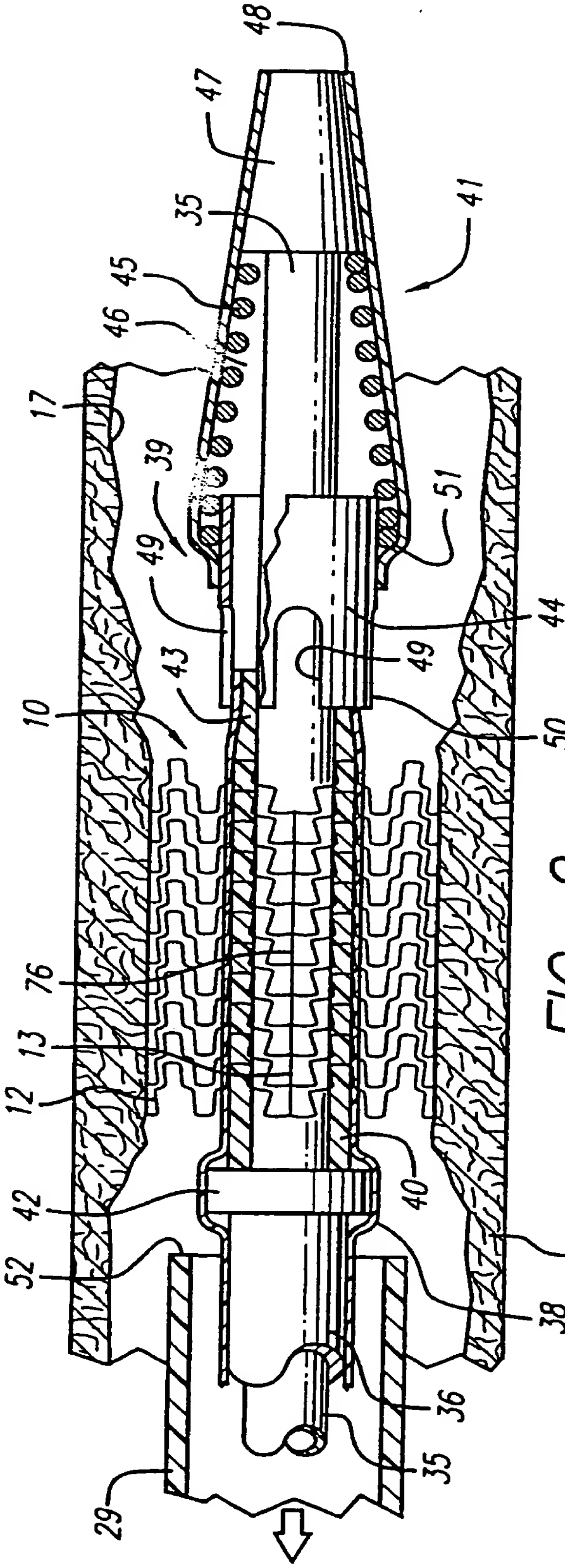
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FIG. 2

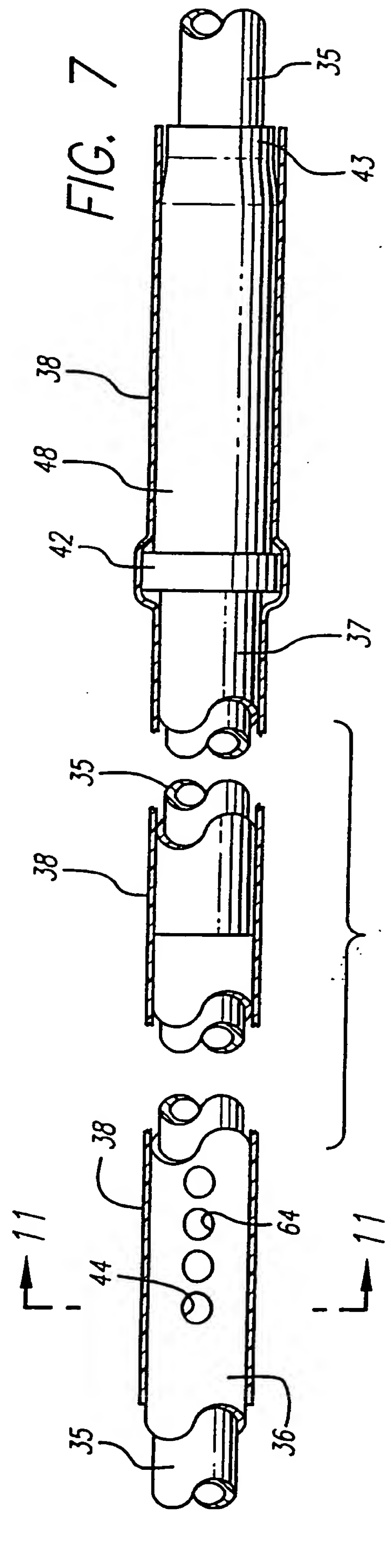
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FIG. 7

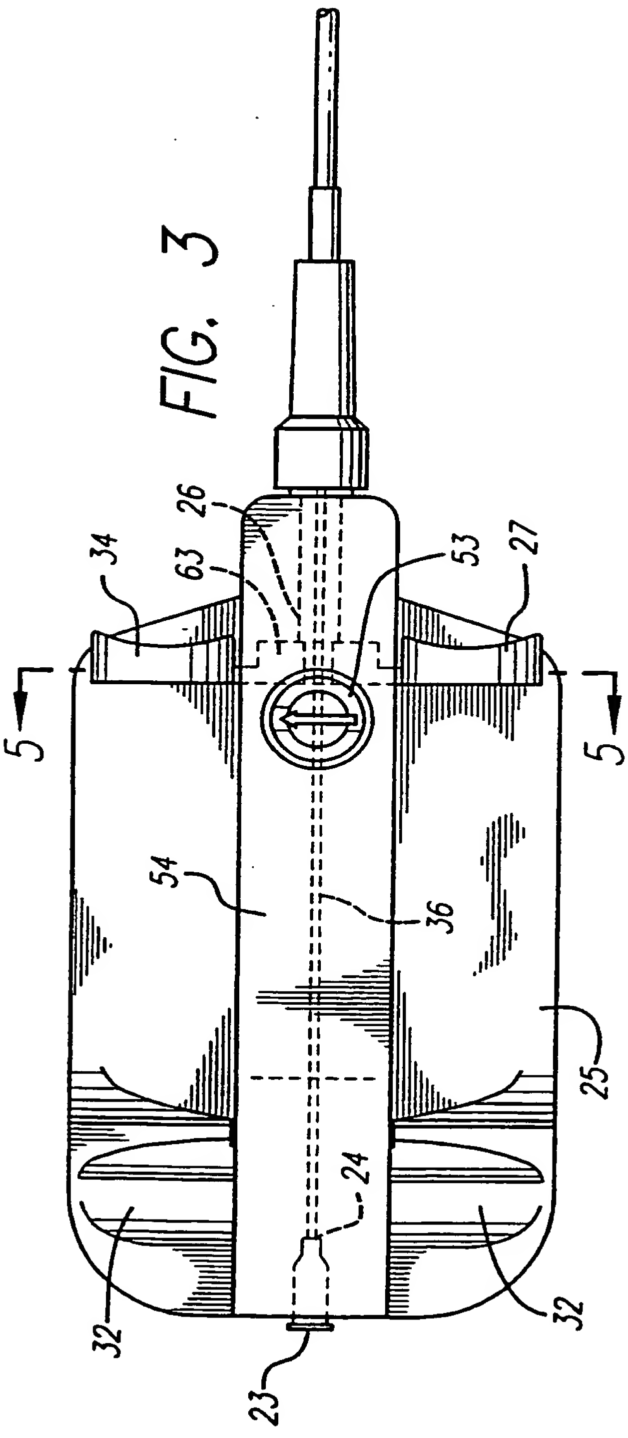
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FIG. 3

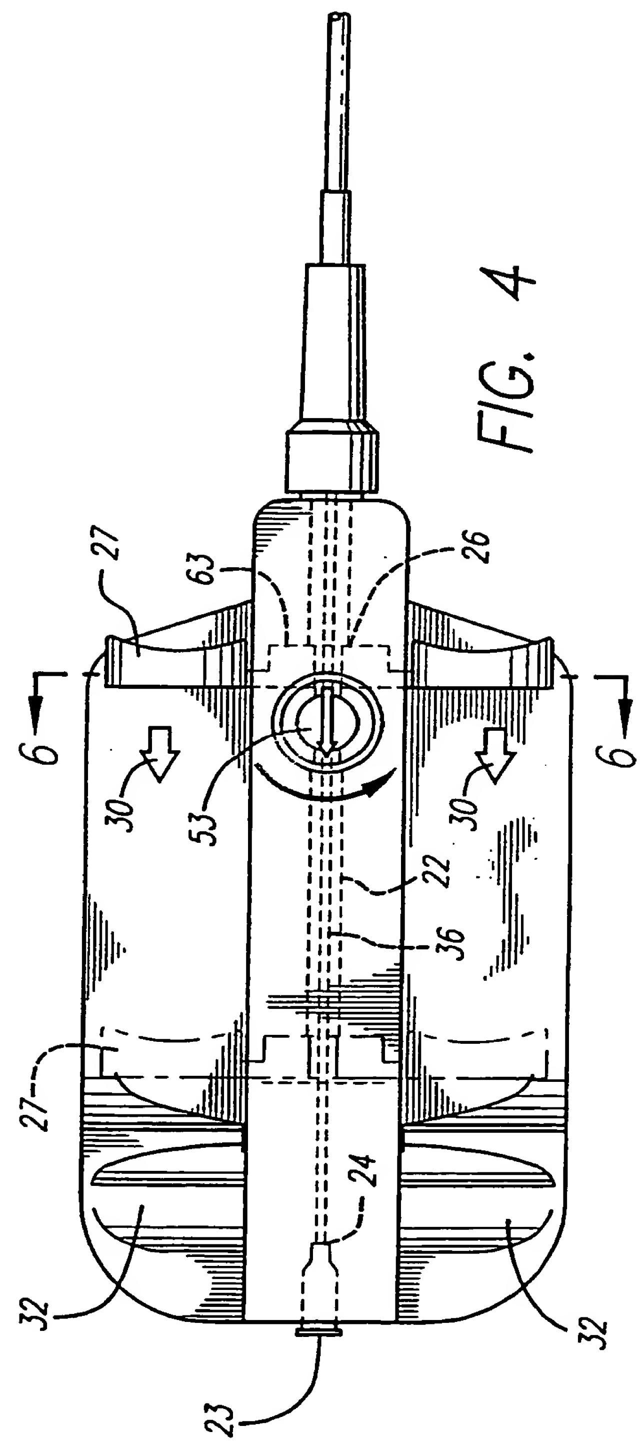
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FIG. 4

FIG. 5

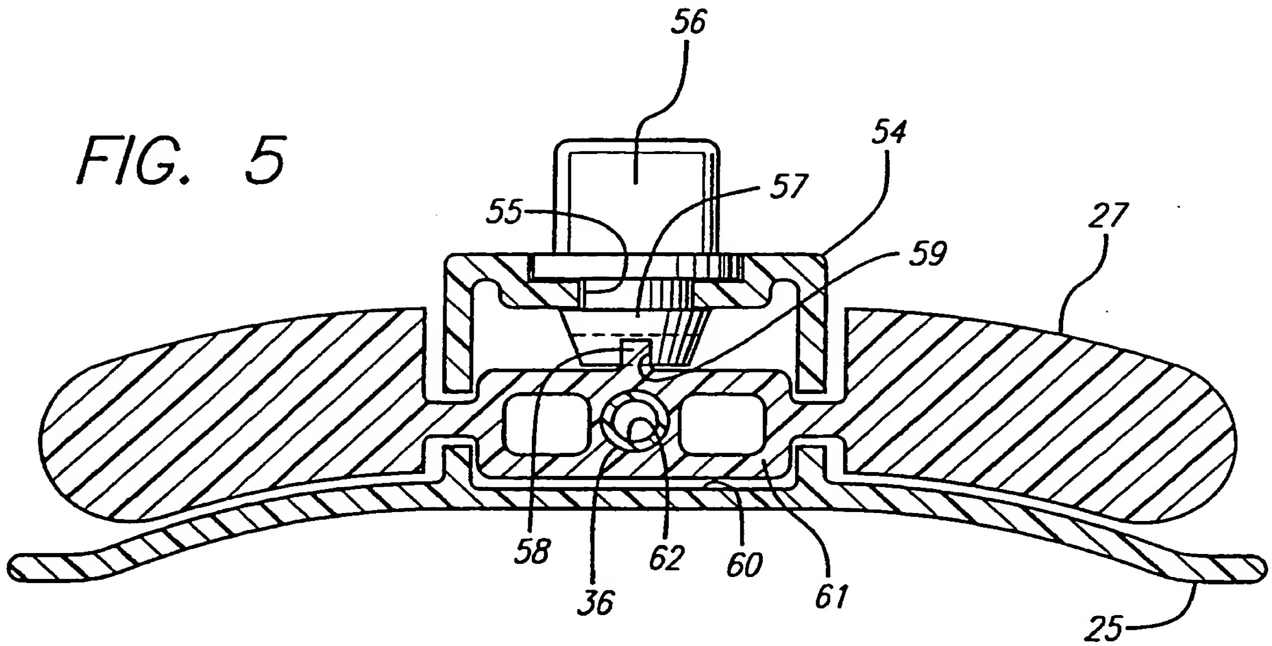
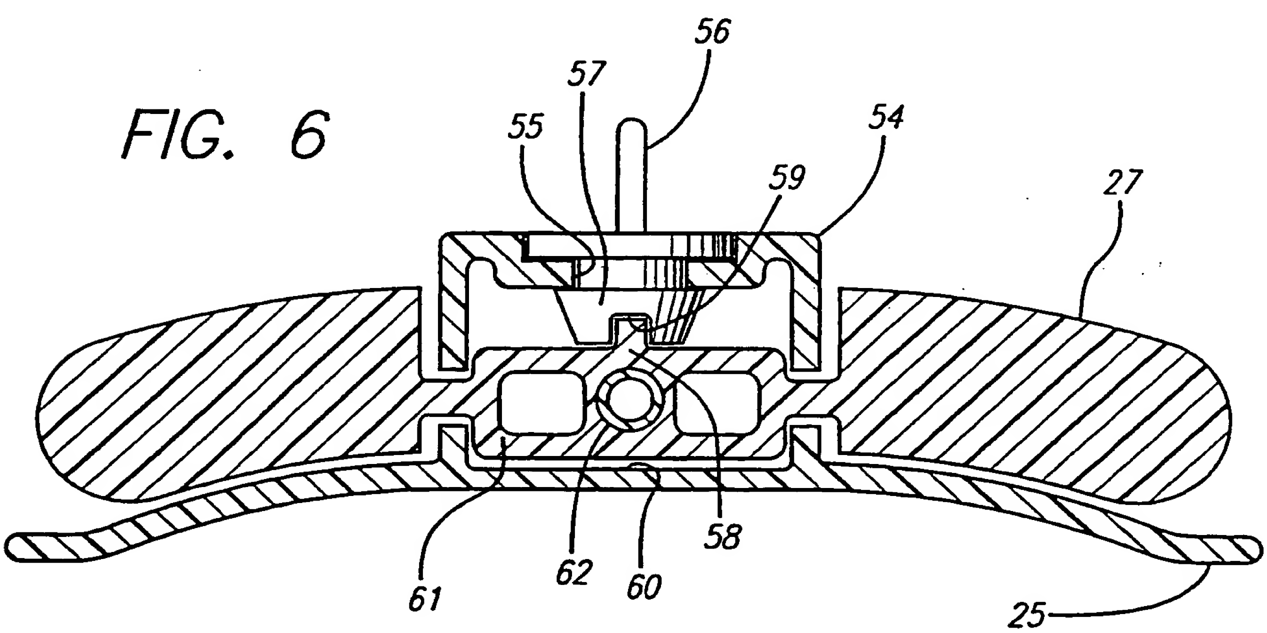


FIG. 6



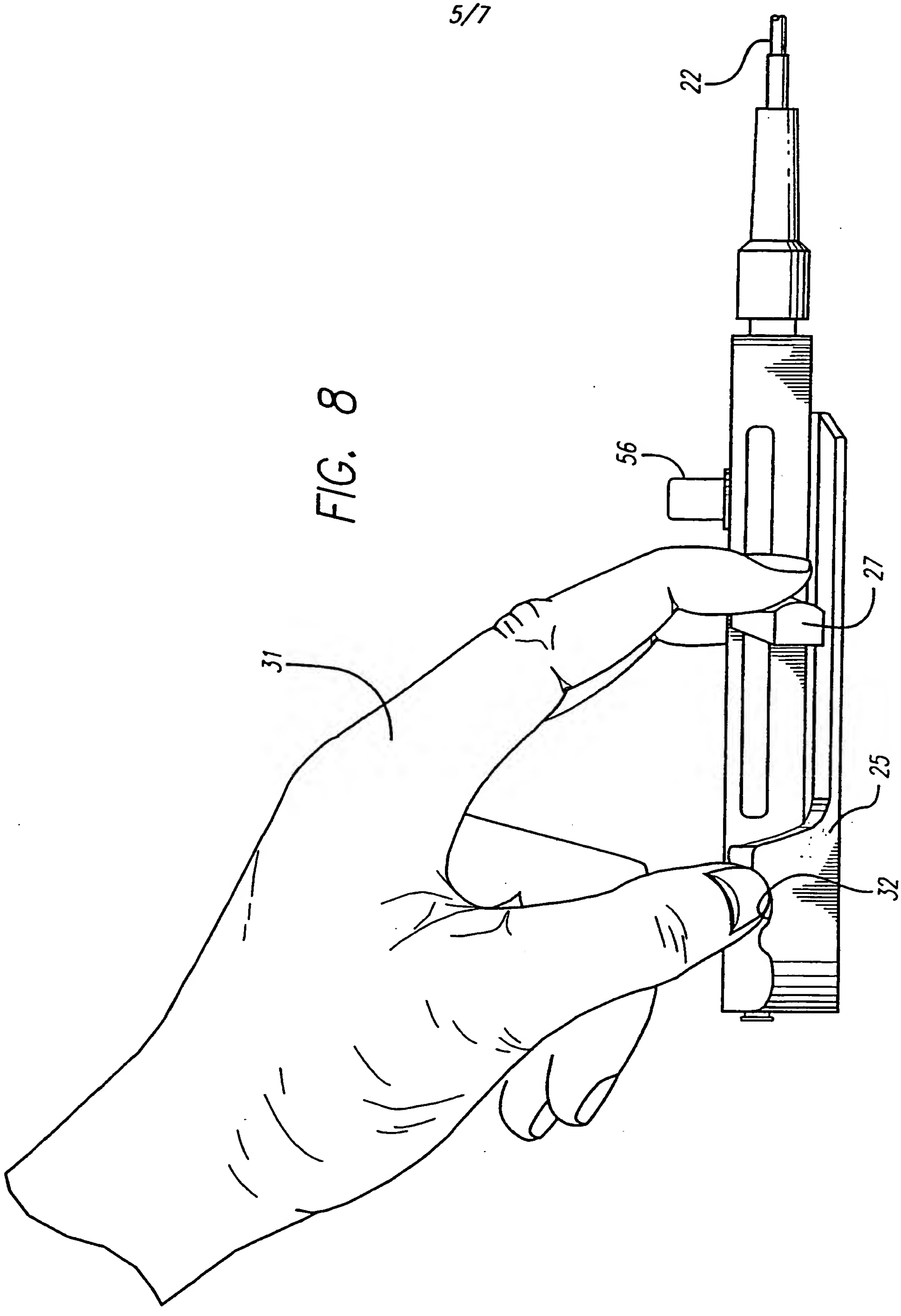


FIG. 8

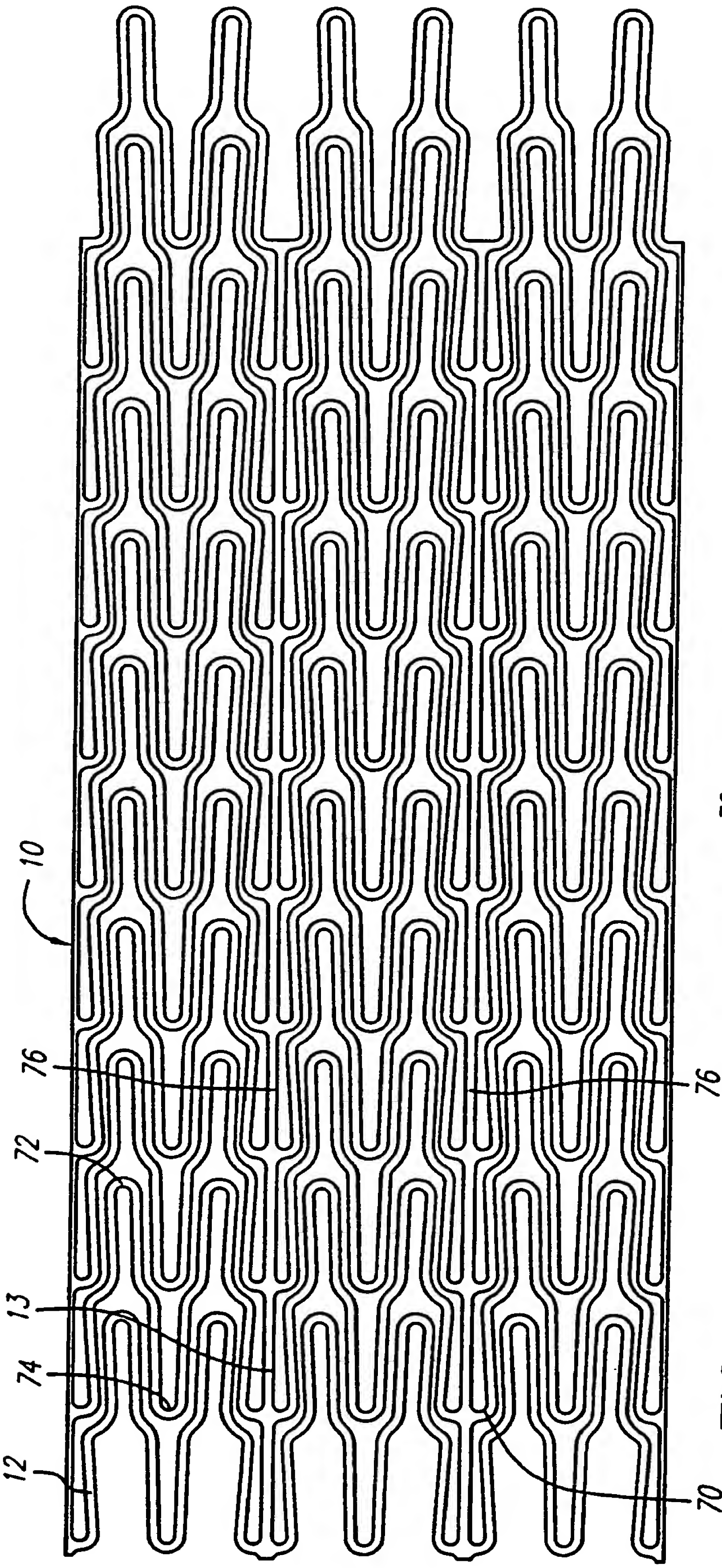


FIG. 9

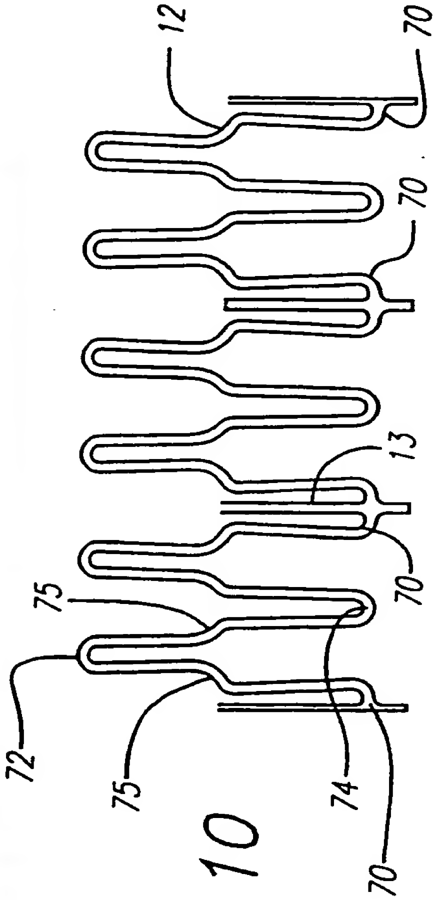


FIG. 10

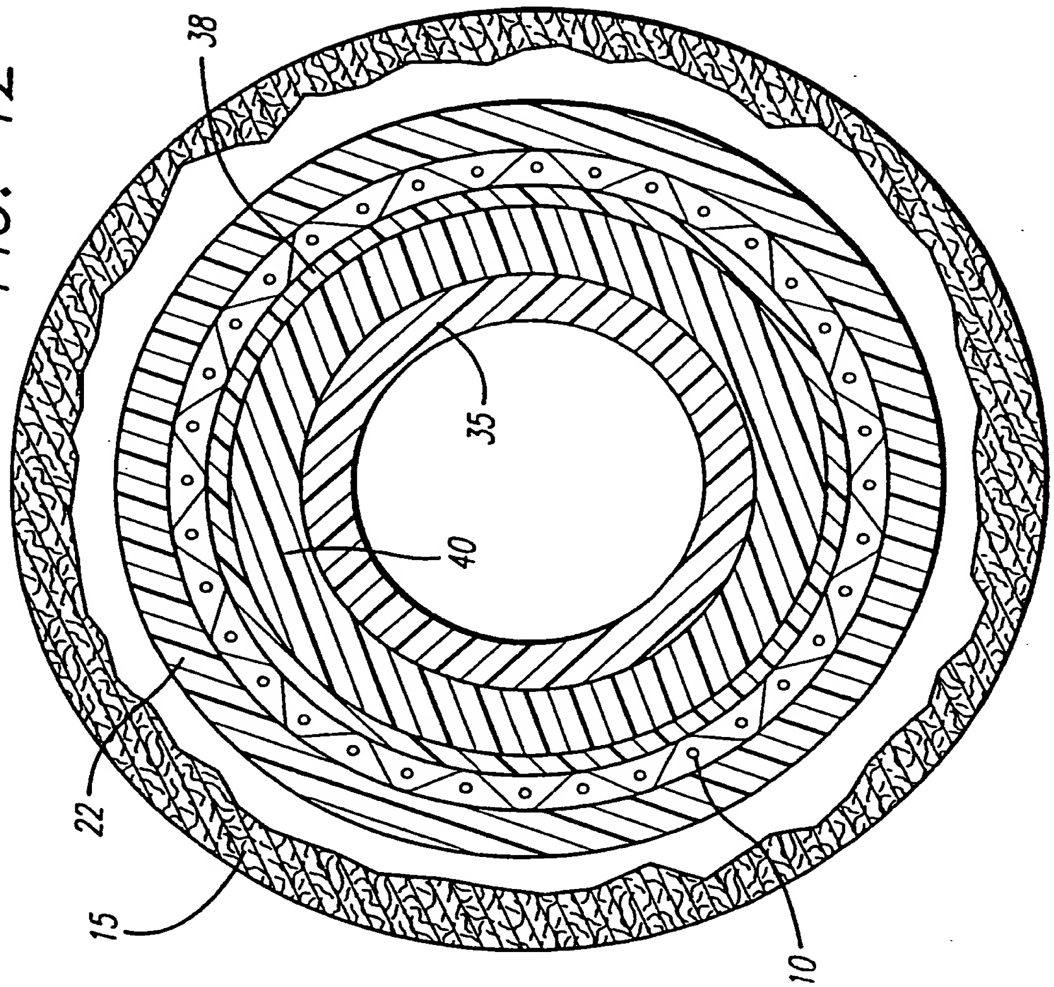


FIG. 12

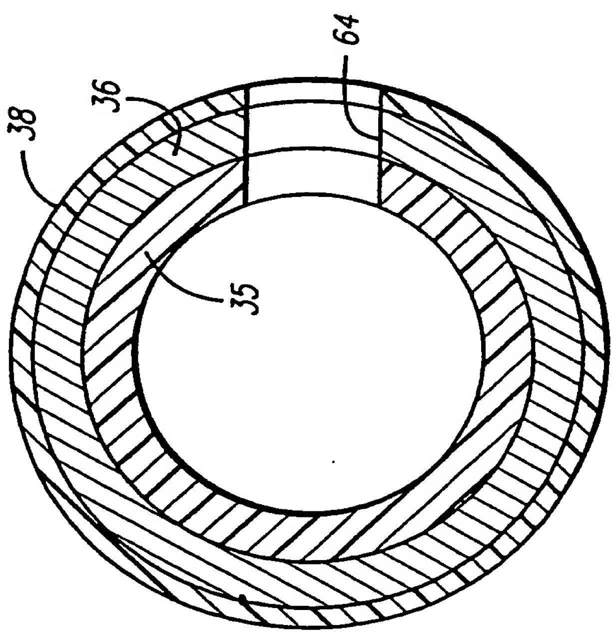


FIG. 11

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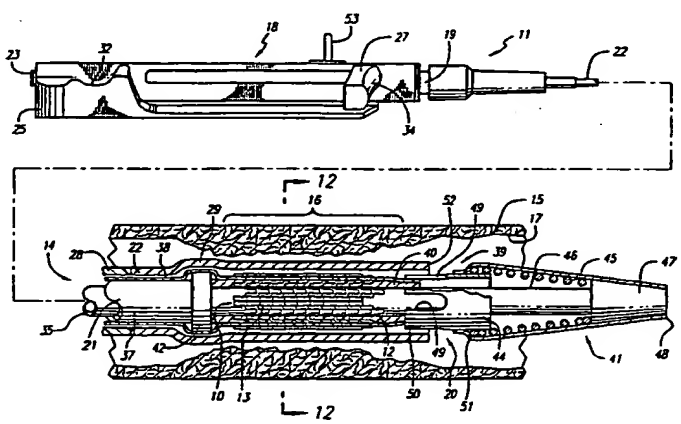
[Continued on next page]

(54) Title: SELF-EXPANDING STENT WITH ENHANCED DELIVERY PRECISION AND STENT DELIVERY SYSTEM



(57) Abstract: The invention is directed to a self-expanding stent (10) for implantation into a body lumen, such as an artery (15). The stent (10) consists of a plurality of radially expandable cylindrical elements (12) generally aligned on a common longitudinal stent axis and interconnected by a plurality of interconnecting members (13) placed on the stent (10) in a collinear arrangement such as to create at least one continuous spine (76) which extends along the length of the stent (10). The invention also is directed to a stent delivery system (11) for implantation of a stent in a vessel which includes an outer tubular member (22) having a restraining sheath (29) and an inner tubular member (21) having a distal end (39) which has a compressed stent (10) mounted thereto. The proximal end (24) of the inner tubular member (21) is connected to a housing assembly (18) which prevents the tubular member (21) from moving when the outer tubular member (22) is retracted to deploy the stent (10). The proximal end (26) of the outer tubular member (22) is attached to a pull-back handle (27) which is slidably mounted on the base (25) of the h using assembly (18). When the pull-back handle (27) is retracted, the restraining sheath (29) is retracted to deploy the sheath, while the inner tubular member (21) remains stationary.

WO 00/69368 A3

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/13570

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 32543 A (DIVYSIO SOLUTIONS LTD ;PENN IAN M (CA); RICCI DONALD R (CA)) 12 September 1997 (1997-09-12) figures 8,10 page 20, line 5 - line 9 page 21, line 22 - line 26	1-7
X	WO 97 25937 A (JANG G DAVID) 24 July 1997 (1997-07-24) claim 10; figures 12,13 page 3, line 28 - line 33	1,4-7
A		2,3

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 November 2000	07 12 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R

Interna. ıal Application No
PCT/US 00/13570

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A		2,3
X	WO 99 15108 A (COOK INC ;MED INST INC (US)) 1 April 1999 (1999-04-01) figures 1,21,22,44-46 page 13, line 29 -page 14, line 4 page 27, line 28 -page 28, line 30 page 38, line 16 - line 19 page 39, line 27 -page 40, line 2	1,4-7
A		2,3
X	US 5 391 172 A (YAMBAO AUGUST ET AL) 21 February 1995 (1995-02-21) figures 1-5 column 2, line 26 -column 4, line 42	8,10
A		9,11,12, 14
X	US 5 507 768 A (SIGWART ULRICH ET AL) 16 April 1996 (1996-04-16) claims 1-5; figures 6,10-12 column 7, line 32 - line 56	8-10
A		14
X	US 5 759 186 A (BACHMANN MICHEL ET AL) 2 June 1998 (1998-06-02) claims 1,6,11; figures 1,6 column 6, line 35 -column 7, line 2	8,10
A		12,15
A	WO 98 52496 A (STRATFORD PETER WILLIAM ;TAYLOR ALISTAIR STEWART (GB); YIANNI YIAN) 26 November 1998 (1998-11-26) claims 1,2,5,10,15; figures 3-8,10 page 12, line 11 -page 12, line 3	8-10,12

3

International application No.
PCT/US 00/13570

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 f first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-7

   A self-expanding stent having
   a plurality of adjacent cylindrical elements made from a self-expanding material, each cylindrical element having a circumference extending around a longitudinal stent axis,
   a plurality of interconnecting members extending between the cylindrical elements, connecting adjacent cylindrical elements to one another, wherein some of the interconnecting members are aligned collinearly with respect to each other to form a continous spine which extends along the length of the stent.

   (Problem: No shortening of the stent during radial expansion for accurate positioning in the vessel)

2. Claims: 8-15

   A stent delivery system having
   a delivery catheter with an inner tubular member having a region for mounting a compressed stent thereon and an outer tubular member having a restraining sheath,
   a housing assembly having a pull-back handle whereby movement of the pull-back handle retracts the sheath proximally from the compressed stent on the inner tubular member.

   (Problem: Easy deployment of the stent in a vessel with one hand only)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. ...al Application No
PCT/US 00/13570

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